

NOT FOR CITATION

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES LLC, et al.,

Plaintiffs,

No. C 03-03817 JSW

v.

COOK INCORPORATED, et al.,

Defendants.

**ORDER GRANTING COOK
INCORPORATED'S MOTION
FOR SUMMARY JUDGMENT OF
NON-INFRINGEMENT**

INTRODUCTION

This matter comes before the Court upon consideration of the Motion for Summary Judgment of Non-Infringement filed by Defendant Cook Incorporated ("Cook"). Having considered the parties' papers, relevant legal authority, the record in this case, and having had the benefit of oral argument, the Court GRANTS Cook's motion.

BACKGROUND

Plaintiffs, Edwards Lifesciences LLC ("Edwards") and Endogad Research PTY Limited ("Endogad") (collectively "Edwards"), filed this suit alleging that Defendants, Cook and W.L. Gore & Associates, Inc. ("Gore"), infringe U.S. Patent Nos. 6,582,458 ("the '458 Patent"), 6,613,073 ("the '073 Patent"), 6,685,736 ("the '736 Patent"), and 6,689,158 ("the '158 Patent") (collectively the "patents-in-suit"). The patents-in-suit relate to devices for treating aneurysms, and in particular abdominal aortic aneurysms, and occlusive disease without resort to "open" surgery.

On March 14, 2007, the Court held a claim construction hearing, pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). On July 23, 2007, the Court issued its Claim Construction Order, in which it construed several of the disputed claim terms to require “malleable” wires. (*See* Claim Construction Order at 13:1-16:8, 17:17-22:11, 24:5-26:11.) In that Order, the Court stated:

[T]he Court concludes that the inventors disclaimed self-expanding wires in the specification. The inventors describe prior art intraluminal grafts as being comprised of “a sleeve in which is disposed a plurality of self expanding wire stents.” (‘458 Patent, col. 1, ll. 20-22.) They then state that “[t]here are a number of problems associated with such known grafts,” including the “lack of precise control of the expansion of the graft in the lumen.” The inventors then state that their invention is “directed to an alternative form of intraluminal grafts which provides an alternative to the known grafts.” (*Id.*, col. 1, ll. 32-42.) Thereafter, the inventors describe the wires that form part of the invention as malleable or state that the device is expanded by use of balloons. (*See, e.g., id.*, col. 1, ll. 49, 60-63, col. 2, ll. 8-15, col. 3, ll. 8-10, col. 5, ll. 32-36, 58-60, 66-67, col. 6, ll. 5-7.) Thus, when the Court reads the claims in light of the specification, it concludes that a person of ordinary skill in the art would clearly understand that this invention requires malleable, rather than resilient, wires.

(Claim Construction Order at 15:21-16:4.)

Edwards accuses four of Cook’s products of infringing the patents-in-suit: the Zenith AAA Endovascular Graft (“AAA Graft”); the Zenith Flex AAA Endovascular Graft (“Flex AAA Graft”); the Zenith Fenestrated AAA Endovascular Graft (“Fenestrated AAA Graft”); and the Zenith TX2 Thoracic TAA Endovascular Graft (“TX2 Graft”). It is undisputed that the accused devices are comprised, in part, of a fabric sleeve that is reinforced with wires both inside and outside of the sleeve. (*See* Declaration of Jeff Nichols in Support of Cook’s Motion for Summary Judgment (“Nichols Decl.”), Exs. C-F (physical samples of accused products).) The focus of Cook’s motion is on the nature of the wires and whether they are “malleable” under the Court’s Claim Construction. Cook asserts they are not. Edwards asserts that they are.

The manner in which Cook’s accused devices are deployed into a patient also is undisputed, with one exception. The accused devices are compressed and constrained within a sheath, which is part of a delivery catheter. This delivery catheter is inserted into a patient’s vessel, pushed to a diseased portion of the vessel, and, after the accused device is positioned satisfactorily, the sheath is withdrawn. As the pressure of the sheath is removed from the

1 accused device, the wires regain their original shape and expand to fit within the vessel. (*See*
2 Nichols Decl., Ex I (October 16, 2007 Deposition of David Biggs (“Biggs Depo. II”) at 75:3-
3 76:11 (describing video of animated deployment of TX2 device, submitted as Exhibit L), 89:12-
4 94:13 (describing video of simulated deployment of TX2 device in glass tube, submitted as
5 Exhibit K); Ex. J (November 2, 2006 Deposition of David Biggs (“Biggs Depo. I”) at 44:16-
6 47:13 (describing TX2 device); Ex. K; Ex. L; Declaration of Tracy Braun in Opposition to
7 Motion for Summary Judgment (“Braun Decl”), Ex Q (Instructions for Use AAA Graft); Ex. R
8 (Instructions for Use TX2 Graft); Ex. S (Instructions for Use Flex AAA Graft); Ex. T
9 (Instructions for Use Fenestrated AAA Graft).) In sum, the wires in Cook’s accused devices
10 initially expand within a vessel because of a release of pressure upon them, rather than by an
11 exertion of pressure upon them.

12 It also is undisputed that a “molding balloon” may be used during deployment and
13 implantation of the accused devices. (*See, e.g.*, Nichols Decl., Ex. J (Biggs Depo. I at 79:5-
14 12).) However, the parties dispute whether the fact that a molding balloon is used during
15 insertion and deployment of the accused devices creates a genuine issue of fact as to whether
16 the wires in Cook’s accused devices are “malleable.”

17 The Court shall discuss additional facts as necessary in the analysis.

18 ANALYSIS

19 A. Legal Standards Applicable to Motions for Summary Judgment.

20 A principal purpose of the summary judgment procedure is to identify and dispose of
21 factually unsupported claims. *Celotex Corp. v. Cattrett*, 477 U.S. 317, 323-24 (1986).
22 Summary judgment is proper when the “pleadings, depositions, answers to interrogatories, and
23 admissions on file, together with the affidavits, if any, show that there is no genuine issue as to
24 any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R.
25 Civ. P. 56(c). “In considering a motion for summary judgment, the court may not weigh the
26 evidence or make credibility determinations, and is required to draw all inferences in a light
27 most favorable to the non-moving party.” *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir.
28 1997).

1 The party moving for summary judgment bears the initial burden of identifying those
2 portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine
3 issue of material fact. *Celotex*, 477 U.S. at 323. An issue of fact is “genuine” only if there is
4 sufficient evidence for a reasonable fact finder to find for the non-moving party. *Anderson v.*
5 *Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). A fact is “material” if it may affect the
6 outcome of the case. *Id.* at 248. If the party moving for summary judgment does not have the
7 ultimate burden of persuasion at trial, that party must produce evidence which either negates an
8 essential element of the non-moving party’s claims or that party must show that the non-moving
9 party does not have enough evidence of an essential element to carry its ultimate burden of
10 persuasion at trial. *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102 (9th Cir.
11 2000). Once the moving party meets his or her initial burden, the non-moving party must go
12 beyond the pleadings and, by its own evidence, “set forth specific facts showing that there is a
13 genuine issue for trial.” Fed. R. Civ. P. 56(e).

14 In order to make this showing, the non-moving party must “identify with reasonable
15 particularity the evidence that precludes summary judgment.” *Keenan v. Allan*, 91 F.3d 1275,
16 1279 (9th Cir. 1996). In addition, the party seeking to establish a genuine issue of material fact
17 must take care to point a court to the evidence precluding summary judgment, because a court is
18 “not required to comb the record to find some reason to deny a motion for summary
19 judgment.” *Carmen v. San Francisco Unified School Dist.*, 237 F.3d 1026, 1029 (9th Cir.
20 2001) (quoting *Forsberg v. Pacific Northwest Bell Telephone Co.*, 840 F.2d 1409, 1418 (9th Cir.
21 1988)). If the non-moving party fails to point to evidence precluding summary judgment, the
22 moving party is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323.

23 **B. Cook’s Motion for Summary Judgment is Granted.**

24 There are two steps in an infringement analysis: (1) construing the claims of the patent
25 in suit; and (2) comparing the properly construed claims to the accused products. *Cybor Corp.*
26 *v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (*en banc*); *see also SafeTCare Mfg.,*
27 *Inc. v. Tele-Made, Inc.*, 497 F.3d 1262, 1268 (Fed. Cir. 2007). The Court has construed the
28

1 claims. Thus, the Court now must determine whether, under its construction, Cook's accused
2 devices fall within the scope of those claims.

3 To meet its burden on the second prong of the infringement analysis, Edwards "'must
4 show the presence of every element or its substantial equivalent in the accused device.'" *Terlep*
5 *v. Brinkman Corp.*, 418 F.3d 1379, 1384 (Fed. Cir. 2005) (quoting *Wolverine World Wide, Inc.*
6 *v. Nike, Inc.*, 38 F.3d 1192, 1199 (Fed. Cir. 1994)). Edwards bears the burden of proving
7 infringement, either literally or under the doctrine of equivalents, by a preponderance of the
8 evidence. *See, e.g., Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir.
9 2000).

10 **1. Edwards Cannot Show that Cook's Accused Devices Literally Infringe the**
11 **Patents-in-Suit.**

12 Cook argues that Edwards cannot show that Cook's accused devices contain malleable
13 wires. "Literal infringement requires the patentee to prove that the accused device contains
14 each limitation of the asserted claim(s). ... If any claim limitation is absent from the accused
15 device, there is no literal infringement as a matter of law." *Bayer AG*, 212 F.3d at 1247
16 (citation omitted). In response, Edwards contends that the plain meaning of the word
17 "malleable" means "capable of being deformed through the application of pressure." (*See*
18 *Braun Decl., Ex. G* (Excerpt of *Stedman's Medical Dictionary*).) Using that definition,
19 Edwards contends that the wires in the accused devices are malleable, because the wires can be
20 shaped into a sinusoidal form before they are attached to graft material. Edwards also argues
21 that the wires may become deformed when the accused devices are inserted into a vessel. (*See,*
22 *e.g., Braun Decl., Ex. C* (Deposition of Roy Greenberg ("Greenberg Depo.") at 108:10-113:21);
23 Declaration of Dr. Kim J. Hodgson in Opposition to Motion for Summary Judgment ("Hodgson
24 Decl."), ¶ 8; Declaration of Charles A. Taylor in Opposition to Motion for Summary Judgment
25 ("Taylor Decl"), ¶¶ 3, 4.)

26 Under a plain meaning of the term "malleable," Edwards' argument might be well
27 taken. In the specification, however, the inventors state that "[t]he wires are maleable [*sic*] and
28 may be bent into any desired shape, *ie they are not resilient to any substantial extent so that*

1 *they have to be physically expanded into contact with the aorta rather than expanding by virtue*
2 *of their own resilience.”* (‘458 Patent, col. 5, ll. 32-35 (emphasis added).) Edwards argues that
3 this phrase should be read to mean that the wires are “(1) malleable (*capable* of being deformed
4 by pressure), (2) *may be bent into any desired shape, and* (3) not resilient (must be physically
5 expanded).” (Opp. Br. at 7:12-15 (emphasis in original).)

6 The Court finds Edwards’ argument unpersuasive, because it ignores the fact that the
7 phrase uses the term “*i.e.*,” not “and.” The term “*i.e.*” is “[a]n abbreviation for ‘*id. est.*,’ that is;
8 that is to say.” See Blacks Law Dictionary at 746 (6th ed. 1990). Thus, by using the signal “*i.e.*”
9 the inventors explained that “malleable” meant “not resilient to any substantial extent so that
10 [the wires] have to be physically expanded into contact with the aorta rather than expanding by
11 virtue of their own resilience.” (‘458 Patent, col. 5, ll. 32-35.) See, e.g., *Abbott Labs v.*
12 *Novopharm Ltd.*, 323 F.3d 1324, 1327, 1330 (Fed. Cir. 2003). The Court relied on the
13 inventors’ definition of malleable when it construed the claims. Further, in light of the
14 inventors’ specific definition of the term malleable, the Court did not include the additional
15 language Cook offered in its proposed construction of the disputed terms, because the Court
16 viewed that language to be surplusage.¹

17 Edwards also contends that even if one does not use the plain meaning of the term
18 malleable, Cook’s accused devices nonetheless infringe the patents-in-suit. As support for this
19 argument, Edwards relies on the fact that the Instructions for Use (“IFUs”) for Cook’s accused
20 devices incorporate the use of a molding balloon once a device is situated within a vessel.
21 Because, according to Edwards, the molding balloon causes the wires to deform and expand
22 into contact with a vessel, the balloon renders the wires a “hybrid of self-expanding and balloon
23 expandable wires.” (Opp. Br. at 16:10-11.) Edwards asserts that as a result, a reasonable jury
24 could conclude that the wires in Cook’s accused devices are malleable.

26 ¹ The Court also notes Edwards’ argument that the independent claims of the
27 patents-in-suit do not include wires. (Opp. Br. at 8:4-6.) However, the Court construed the
28 patents-in-suit to cover intraluminal devices, which all parties agreed required wires as a
component. The Court also rejected Edwards’ arguments that the claims could encompass a
previously implanted traditional vascular graft. The Court finds no basis to modify its
previous construction of the claims.

1 In support of this argument, Edwards proffers the declaration of Dr. Kim J. Hodgson,
2 “a practicing vascular surgeon and Director of the Endovascular Therapy Program, Division of
3 Peripheral Vascular Surgery, at Southern Illinois University School of Medicine.” (Hodgson
4 Decl., ¶ 1.) Dr. Hodgson, who has used Cook’s accused devices, avers that “[a]fter initial
5 opening of the devices, and placement of the bifurcated main body and iliac extenders into
6 position inside the vessels of the patient, a separate balloon is then endovascularly positioned
7 and inflated to further expand the wires and graft. The Cook Zenith, Flex and Fenestrated IFUs
8 teach that the balloon should be expanded in the ‘balloon expansion/graft sealing sites.’ ... The
9 Cook TX2 IFUs teach that a balloon should be expanded in the ‘overlap and landing zones.’”
10 (Hodgson Decl., ¶ 4, Exs. H-K (IFUs).) Dr. Hodgson also avers that Cook representatives have
11 “insisted upon following the FDA IFUs that require the surgeon to use a balloon to seal the
12 overlap sites,” and that he personally does so “to fully expand the wires and graft material and
13 seal all of the overlap areas and the areas adjacent to the vessel wall in the overwhelming
14 majority of my cases.” (*Id.*, ¶ 5.)

15 Edwards also proffers a declaration from Dr. Charles Taylor, who is an Associate
16 Professor at Stanford University in the Departments of Bioengineering, Surgery, Mechanical
17 Engineering, Pediatrics, and Radiology. (Taylor Decl., ¶ 1.) Dr. Taylor avers that “the
18 expansion of the graft material” in Cook’s accused devices “likely causes expansion of the
19 wires because the wires are tightly sutured to the graft. This is particularly true in the overlap
20 region of the two graft portions, which are not typically placed against a vessel wall, or in the
21 case where a balloon is used to fix a leak. Thus, expansion of the balloon would be a
22 meaningless step if the graft and wires were not caused to expand.” (*Id.*, ¶ 15.) Dr. Taylor
23 opines that, “if the term ‘malleable’ is interpreted to require balloon expansion, the wires in the
24 accused products are ‘malleable’ because they are potentially expandable by a balloon when
25 placed into the patient’s vessel,” and also opines that Cook’s accused devices literally infringe
26 the claims of the patents-in-suit. (*Id.*)

27 Edwards also notes that Dr. Roy Greenberg, who describes himself as part of the team
28 who worked to develop the accused devices, and who Cook describes as an “expert” in the use

1 of the Zenith device, authored a publication in which he stated that “[a] compliant balloon was
2 inflated at the joints and sealing point to ensure adequate expansion.” (Braun Decl., Ex. C
3 (Greenberg Depo. at 44:24-45:12); Ex. U (Biggs Depo. I at 41:9-17); Ex. V (Greenberg, R.
4 “*The Zenith Endovascular Graft : Results of A United States Multicenter Trial*” at COOK
5 041734); *see also id.*, Exs. Y, Z.)² Finally, Edwards submits an internal Edwards memorandum,
6 in which it distinguishes its devices from its competitors’ devices as follows:

7 The Baxter Endovascular AAA Graft is a balloon deployed device. The
8 device is fully expanded and anchored upon primary inflation of the balloon.
9 All competitive devices at this point are based upon self expanding metals
10 being used as the stent material which then require a secondary balloon
11 expansion to anchor and mold the graft to the aortic anatomy. The secondary
12 balloon inflation carries risk and required additional time on the part of the
13 clinician to deploy the self expanding device. Second, self expanding
14 devices and their expansion are very difficult to control as they are deployed.
15 Because our device is balloon expandable, expansion is controlled by the rate
16 of the inflation of the balloon.

17 (Braun Decl., Ex. N.)

18 Cook contends that the molding balloon does not cause the wires to expand. Rather, it
19 is used to “iron” the graft material and “to ensure that there are not pleats or creases in the graft
20 that might lead to ... endo leaks,” or to further seat the accused device if there is “thrombus or
21 other external material present that would prevent that stent from fully opening.” (*See* Nichols
22 Decl., Ex. I (Biggs Depo. II at 73:8-19); Braun Decl., Ex. U (Biggs Depo. II at 24:16-20).) For
23 example, when Dr. Greenberg was questioned about whether the stent portion of the accused
24 device would expand if someone were to “expand the balloon beyond just a tiny amount for the
25 ironing,” he stated it would not. (Braun Decl., Ex. C (Greenberg Depo. at 143:5-144:25).) Dr.
26 Greenberg, however, did agree that the wires are attached to the fabric, but stated that fact did
27 not necessarily mean that the wires would move when the fabric moved. (*Id.* at 145:1-19.)

28 Cook also contends that the diameter of the accused devices is designed to be larger
than the vessels into which they are inserted. According to Cook, the larger diameter enables

² When questioned about this publication, Dr. Greenberg stated that “I don’t generally refer to expansion. I don’t use the term expansion with a compliant balloon, it is more of an ironing of the fabric.” (Braun Decl., Ex. C (Greenberg Depo. at 140:4-141:3).)

1 the accused device to fit securely within any given vessel once the wires expand upon removal
2 from the sheath. (Nichols Decl., Ex. J (Biggs Depo. I at 79:19-25, 85:15-86:6).)

3 Even taking the evidence regarding the use of the molding balloon in the light most
4 favorable to Edwards, the Court concludes that it demonstrates only that once the accused
5 devices have been placed within a vessel and the wires have expanded *on their own*, the
6 molding balloon may be used to finish a seal or straighten out the fabric body of a graft.
7 However, the definition of malleable in the patents-in-suit focuses on the manner in which the
8 wires expand and whether they are capable of expanding without the exertion of pressure upon
9 them. Under the Court's construction of the claims, the Court concludes that no reasonable jury
10 could conclude that Cook's accused devices contain "malleable" wires. Cook, therefore, is
11 entitled to judgment in its favor on this basis.

12 **2. Edwards Cannot Show the Accused Devices Infringe the Patents-in-Suit**
13 **Under the Doctrine of Equivalents.**

14 "Under the doctrine of equivalents, 'a product or process that does not literally infringe
15 upon the express terms of a patent claim may nonetheless be found to infringe if there is
16 equivalence between the elements of the accused product or process and the claimed elements
17 of the patented invention.'" *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350,
18 1357 (Fed. Cir. 2005) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17,
19 21 (1997)).

20 The doctrine of equivalents thereby recognizes that:

21 [t]he language in the patent claims may not capture every nuance of the
22 invention or describe with complete precision the range of its novelty. If
23 patents were always interpreted by their literal terms, their value would be
24 greatly diminished. Unimportant and insubstantial substitutes for certain
25 elements could defeat the patent, and its value to inventors could be
destroyed by simple acts of copying. For this reason, the clearest rule of
patent interpretation, literalism, may conserve judicial resources but is not
necessarily the most efficient rule. The scope of a patent is not limited to its
literal terms but instead embraces all equivalents described.

26 *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). Although a
27 patentee is entitled to argue that an accused device is equivalent to his or her claimed invention,
28 the ability to argue infringement by equivalence is not without limitations.

1 One limit on the doctrine of equivalents is the “all elements” rule. The “all
2 elements” rule attempts to balance the doctrine of equivalents with the basic
3 patent law principle that claim language defines the scope of an invention
4 and every limitation is material.

5 Each element contained in a patent claim is deemed material to
6 defining the scope of the patented invention, and thus the doctrine of
7 equivalents must be applied to individual elements of the claim, not
8 to the invention as a whole. It is important to ensure that the
9 application of the doctrine, even as to an individual element, is not
10 allowed such broad play as to effectively eliminate that element in its
11 entirety.

12 *Warner-Jenkinson*, 520 U.S. at 29. Thus, as a practical matter, the “all
13 elements” rule informs a doctrine of equivalents analysis by requiring that
14 equivalence be assessed on a limitation-by-limitation basis, rather than from
15 the perspective of the invention as a whole, and that no limitation be read
16 completely out of the claim. [*Freedman Seating Co.*, 420 F.3d at 1358.]

17 In *Warner-Jenkinson*, the Supreme Court provided guidance for determining
18 when resort to the doctrine of equivalents is precluded as a matter of law.
19 First, the Court noted that “[w]here the evidence is such that no reasonable
20 jury could determine two elements to be equivalent, district courts are
21 obliged to grant partial or complete summary judgment.” *Warner-Jenkinson*,
22 520 U.S. at 39 (citing Fed. R. Civ. P. 56; *Celotex*, 477 U.S. at 322-23)).
23 Second, the Court noted that “under the particular facts of a case, ... if a
24 theory of equivalence would entirely vitiate a particular claim element,
25 partial or complete judgment should be rendered by the court.” *Id.* at 39 n.8.

26 *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1016 (Fed. Cir. 2006).

27 The Federal Circuit has noted that “[t]here is no set formula for determining whether a
28 finding of equivalence would vitiate a claim limitation, and thereby violate the all limitations
rule. Rather, courts must consider the totality of the circumstances in each case and determine
whether the alleged equivalent can be fairly characterized as an insubstantial change from the
claimed subject matter without rendering the pertinent limitation meaningless.” *Freedman*
Seating, 420 F.3d at 1359.

Edwards argues that “resilient” wires can perform the same function as “malleable”
wires with the same result. *See Warner-Jenkinson*, 520 U.S. at 39-40. Edwards offers the
opinion of Dr. Taylor, who contends that the wires in Cook’s accused devices are equivalent to
the wires in the patents-in-suit and avers that the resilient wires in Cook’s products “provide a
flexible structure that permits one individual part of the graft to be overlapped and anchored
within the other individual part of the graft.” (Taylor Decl., ¶ 16.) He further avers that Cook’s

1 resilient wires perform this function by expanding within a vessel to form a seal at a section
2 where the graft might not be supported by a vessel and to provide support along the length of
3 the graft. (*Id.*)

4 The Court finds Edwards' argument on the doctrine of equivalents to be analogous to
5 the argument presented to, and rejected by, the Federal Circuit in *Tronzo v. Biomet, Inc.*, 156
6 F.3d 1154 (Fed. Cir. 1998). In that case, the claims of the patent-in-suit were directed to
7 "artificial hip sockets that include cup implants adapted for insertion into an acetabular, or hip,
8 bone." *Id.* at 1156. Two of the asserted claims required a conical shaped cup, but the plaintiff
9 argued at trial that the defendant's hemispherical shaped cup functioned in the same way as a
10 conically shaped cup, and the jury agreed. *Id.* at 1160. On appeal, the Federal Circuit
11 concluded that to find that "any shape would be equivalent to the conical limitation," would
12 vitiate that claim limitation and would violate the all-elements rule. *Id.* Here too, Edwards'
13 argument is premised upon a finding that any wire would be the equivalent of a "malleable"
14 wire. If, however, the Court were to adopt that argument and conclude that "resilient" wires
15 would be equivalent to "malleable" wires, it would vitiate the malleable limitation the Court
16 concluded is required by the claims.

17 Furthermore, the Court also concluded that Edwards disclaimed the use of resilient
18 wires. When a patentee has disavowed or disclaimed certain subject matter from the scope of
19 the claims, that subject matter cannot be considered an equivalent. *See J&M Corp. v. Harley*
20 *Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed. Cir. 2001) ("The scope of equivalents may [] be
21 limited by statements in the specification that disclaim coverage of certain subject matter.")
22 Edwards argues that the Court erred, because the specification of the patents-in-suit refer to a
23 resilient wire in the "skirt" portion of a trouser-type graft. (*See* '485 Patent, col. 4, ll. 33-49.)
24 Edwards also argues that "if we disclaim self-expanding wires, we can't use self-expanding
25 wires. That construction means that the White and Yu graft – the commercial embodiment is
26 not covered by the patent. That means the preferred embodiment is not covered by the patent."
27 (Feb. 1, 2008 Transcript at 16:14-19.)
28

Thereafter, the inventors note that “[i]n those cases where one graft according to this invention is to be inserted into the downstream end of another such graft it may be desirable to provide means to stop the ‘skirt’ from being distorted by the insertion of the one graft.” (*Id.*, col. 4, ll. 33-37.) The inventors then state that the means for achieving this result may be either that “the skirt ... be provided with a small number of linear reinforcement wires extending longitudinally of the graft” or that “the skirt ... be provided with at least one resilient annular reinforcement wire ... [which] will spring into an expanded condition upon being released from the catheter through which it is introduced into the body.” (*Id.*, col. 4, ll. 37-49.) Although the Court reiterates its conclusion that the inventors disclaimed the use of resilient wires in favor of malleable wires, the Court finds that that disclaimer would not preclude the inventors from claiming resilient wires in the skirt portion of the graft as “means to stop the ‘skirt’ from being distorted by the insertion of the one graft.”

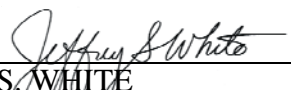
CONCLUSION

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1 for March 28, 2008 at 9:00 a.m., and shall submit an updated case management conference
2 statement in light of this Order.

3 **IT IS SO ORDERED.**

4 Dated: March 18, 2008



JEFFREY S. WHITE
UNITED STATES DISTRICT JUDGE